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Environmental Health Criteria 238

EXTREMELY LOW FREQUENCY FIELDS

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PREAMBLE

The WHO Environmental Health Criteria Programme

In 1973 the World Health Organization (WHO) Environmental Health Criteria Programme was initiated with the following objectives:

- (i) to assess information on the relationship between exposure to environmental pollutants and human health, and to provide guidelines for setting exposure limits;
- (ii) to identify new or potential pollutants;
- (iii) to identify gaps in knowledge concerning the health effects of pollutants;
- (iv) to promote the harmonization of toxicological and epidemiological methods in order to have internationally comparable results.

It should be noted in this context that WHO defines health as the state of complete physical, mental and social well being and not merely the absence of disease or infirmity (WHO, 1946).

The first Environmental Health Criteria (EHC) monograph, on mercury, was published in 1976 and since that time an ever-increasing number of assessments of chemical and of physical agents have been produced. In addition, many EHC monographs have been devoted to evaluating toxicological methodology, e.g. for genetic, neurotoxic, teratogenic and nephrotoxic agents. Other publications have been concerned with epidemiological guidelines, evaluation of short-term tests for carcinogens, biomarkers, effects on the elderly and so forth.

The original impetus for the Programme came from World Health Assembly resolutions and the recommendations of the 1972 UN Conference on the Human Environment. Subsequently the work became an integral part of the International Programme on Chemical Safety (IPCS), a cooperative programme of the United Nations Environment Programme (UNEP), the International Labour Office (ILO) and WHO. With the strong support of the new partners, the importance of occupational health and environmental effects was fully recognized. The EHC monographs have become widely established, used and recognized throughout the world.

Electromagnetic Fields

Three monographs on electromagnetic fields (EMF) address possible health effects from exposure to extremely low frequency (ELF) fields, static and ELF magnetic fields, and radiofrequency (RF) fields (WHO, 1984; WHO, 1987; WHO, 1993). They were produced in collaboration with UNEP, ILO and the International Non-Ionizing Radiation Committee (INIRC) of the International Radiation Protection Association (IRPA) and from 1992 the International Commission on Non-Ionizing Radiation Protection (ICNIRP).

EHC monographs are usually revised if new data are available that would substantially change the evaluation, if there is public concern for health or environmental effects of the agent because of greater exposure, or if an appreciable time period has elapsed since the last evaluation. The EHCs on EMF are being revised and will be published as a set of three monographs spanning the relevant EMF frequency range (0–300 GHz); static fields (0 Hz), ELF fields (up to 100 kHz, this volume) and RF fields (100 kHz – 300 GHz).

WHO's assessment of any health risks produced by non-ionizing radiation emitting technologies (in the frequency range 0–300 GHz) falls within the responsibilities of the International EMF Project. This Project was established by WHO in 1996 in response to public concern over health effects of EMF exposure, and is managed by the Radiation and Environmental Health Unit (RAD) which is coordinating the preparation of the EHC Monographs on EMF.

The WHO health risk assessment exercise includes the development of an extensive database that comprises relevant scientific publications. Interpretation of these studies can be controversial, as there exists a spectrum of opinion within the scientific community and elsewhere. In order to achieve as wide a degree of consensus as possible, the health risk assessment also draws on, and in some cases includes sections of, reviews already completed by other national and international expert review bodies, with particular reference to:

- the International Agency for Research on Cancer (IARC)
 Monograph on static and extremely low frequency (ELF) fields
 IARC, 2002. In June 2001 IARC formally evaluated the evidence
 for carcinogenesis from exposure to static and ELF fields. The
 review concluded that ELF magnetic fields are possibly
 carcinogenic to humans.
- Reviews on physics/engineering, biology and epidemiology commissioned by WHO to the International Commission on Non-Ionizing Radiation Protection (ICNIRP), a non-governmental organization in formal relations with WHO (ICNIRP, 2003).
- Reviews by the Advisory Group on Non-Ionising Radiation (AGNIR) of the Health Protection Agency (HPA), United Kingdom (AGNIR, 2001a; 2001b; 2004; 2006).

Scope

The EHC monographs are intended to provide critical reviews on the effect on human health and the environment of chemicals, physical and biological agents. As such, they include and review studies that are of direct relevance for the evaluation. However, they do not describe *every* study carried out. Worldwide data are used and are quoted from original studies, not from abstracts or reviews. Both published and unpublished reports are considered but preference is always given to published data. Unpublished data

are only used when relevant published data are absent or when they are pivotal to the risk assessment. A detailed policy statement is available that describes the procedures used for unpublished proprietary data so that this information can be used in the evaluation without compromising its confidential nature (WHO, 1990).

In the evaluation of human health risks, sound human data, whenever available, are generally more informative than animal data. Animal and in vitro studies provide support and are used mainly to supply evidence missing from human studies. It is mandatory that research on human subjects is conducted in full accord with ethical principles, including the provisions of the Helsinki Declaration (WMA, 2004).

All studies, with either positive or negative effects, need to be evaluated and judged on their own merit, and then all together in a weight of evidence approach. It is important to determine how much a set of evidence changes the probability that exposure causes an outcome. Generally, studies must be replicated or be in agreement with similar studies. The evidence for an effect is further strengthened if the results from different types of studies (epidemiology and laboratory) point to the same conclusion.

The EHC monographs are intended to assist national and international authorities in making risk assessments and subsequent risk management decisions. They represent an evaluation of risks as far as the data will allow and are not, in any sense, recommendations for regulation or standard setting. These latter are the exclusive purview of national and regional governments. However, the EMF EHCs do provide bodies such as ICNIRP with the scientific basis for reviewing their international exposure guidelines.

Procedures

The general procedures that result in the publication of this EHC monograph are discussed below.

A first draft, prepared by consultants or staff from a RAD Collaborating Centre, is based initially on data provided from reference databases such as Medline and PubMed and on IARC and ICNIRP reviews. The draft document, when received by RAD, may require an initial review by a small panel of experts to determine its scientific quality and objectivity. Once the document is acceptable as a first draft, it is distributed, in its unedited form, to well over 150 EHC contact points throughout the world who are asked to comment on its completeness and accuracy and, where necessary, provide additional material. The contact points, usually designated by governments, may be Collaborating Centres, or individual scientists known for their particular expertise. Generally some months are allowed before the comments are considered by the author(s). A second draft incorporating comments received and approved by the Coordinator (RAD), is then distributed to Task Group members, who carry out the peer review, at least six weeks before their meeting.

The Task Group members serve as individual scientists, not as representatives of their organization. Their function is to evaluate the accuracy, significance and relevance of the information in the document and to assess the health and environmental risks from exposure to the part of the electromagnetic spectrum being addressed. A summary and recommendations for further research and improved safety aspects are also required. The composition of the Task Group is dictated by the range of expertise required for the subject of the meeting (epidemiology, biological and physical sciences, medicine and public health) and by the need for a balance in the range of opinions on the science, gender and geographical distribution.

The membership of the WHO Task Groups is approved by the Assistant Director General of the Cluster on Sustainable Development and Health Environments. These Task Groups are the highest level committees within WHO for conducting health risk assessments.

Task Groups conduct a critical and thorough review of an advanced draft of the ELF EHC monograph and assess any risks to health from exposure to both electric and magnetic fields, reach agreements by consensus, and make final conclusions and recommendations that cannot be altered after the Task Group meeting.

The World Health Organization recognizes the important role played by non-governmental organizations (NGOs). Representatives from relevant national and international associations may be invited to join the Task Group as observers. While observers may provide a valuable contribution to the process, they can only speak at the invitation of the Chairperson. Observers do not participate in the final evaluation; this is the sole responsibility of the Task Group members. When the Task Group considers it to be appropriate, it may meet *in camera*.

All individuals who as authors, consultants or advisers participate in the preparation of the EHC monograph must, in addition to serving in their personal capacity as scientists, inform WHO if at any time a conflict of interest, whether actual or potential, could be perceived in their work. They are required to sign a conflict of interest statement. Such a procedure ensures the transparency and probity of the process.

When the Task Group has completed its review and the Coordinator (RAD) is satisfied as to the scientific consistency and completeness of the document, it then goes for language editing, reference checking, and preparation of camera-ready copy. After approval by the Director, Department of Protection of the Human Environment (PHE), the monograph is submitted to the WHO Office of Publications for printing. At this time a copy of the final draft is sent to the Chairperson and Rapporteur of the Task Group to check the proofs.

Extremely Low Frequency Environmental Health Criteria

This EHC addresses the possible health effects of exposure to extremely low frequency (>0 Hz -100 kHz) electric and magnetic fields. By

far the majority of studies concern the health effects resulting from exposure to power frequency (50–60 Hz) magnetic fields; a few studies address the effects of exposure to power frequency electric fields. In addition, a number of studies have addressed the effects of exposure to the very low frequency (VLF, 3–30 kHz) switched gradient magnetic fields used in Magnetic Resonance Imaging, and, more commonly, the weaker VLF fields emitted by visual display units (VDU's) and televisions.

The ELF EHC is organized by disease category; separate expert working groups met in order to develop drafts addressing neurodegenerative disorders (Chapter 7), cardiovascular disorders (Chapter 8), childhood leukaemia (section 11.2.1) and protective measures (Chapter 13). The membership of these expert working groups is given below. Drafts of the other chapters were prepared by consultants, staff from WHO collaborating centres and by RAD Unit staff. These included Prof. Paul Elliot, Imperial College of Science, Technology and Medicine, UK, Prof. Maria Stuchly, University of Victoria, Canada, and Prof. Bernard Veyret, ENSCPB, France, in addition to individuals who were also members of one of the expert working groups and/or the Task Group (see below). The draft chapters were individually reviewed by external referees prior to their collation as a draft document.

The draft EHC was subsequently distributed for external review. Editorial changes and minor scientific points were addressed by a WHO Editorial Group and the final draft was distributed to Task Group members prior to the Task Group meeting.

The Task Group met from October 3–7, 2005 at WHO headquarters in Geneva. The text of the EHC was subsequently edited for clarity and consistency by an Editorial Group consisting of Dr Emilie van Deventer and Dr Chiyoji Ohkubo, both from WHO, Geneva, Switzerland, Dr Rick Saunders, Health Protection Agency, Chilton, UK, Dr Eric van Rongen, Health Council of the Netherlands, Prof. Leeka Kheifets, UCLA School of Public Health, Los Angeles, CA, USA and Dr Chris Portier, NIEHS, Research Triangle Park, NC, USA. Following a final review by the Task Group and scientific and text editing, the EHC was published on the International EMF Projects website on 18 June 2007.

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1 SUMMARY AND RECOMMENDATIONS FOR FURTHER STUDY

This Environmental Health Criteria (EHC) monograph addresses the possible health effects of exposure to extremely low frequency (ELF) electric and magnetic fields. It reviews the physical characteristics of ELF fields as well as the sources of exposure and measurement. However, its main objectives are to review the scientific literature on the biological effects of exposure to ELF fields in order to assess any health risks from exposure to these fields and to use this health risk assessment to make recommendations to national authorities on health protection programs.

The frequencies under consideration range from above 0 Hz to 100 kHz. By far the majority of studies have been conducted on power-frequency (50 or 60 Hz) magnetic fields, with a few studies using power-frequency electric fields. In addition, there have been a number of studies concerning very low frequency (VLF, 3–30 kHz) fields, switched gradient magnetic fields used in magnetic resonance imaging, and the weaker VLF fields emitted by visual display units and televisions.

This chapter summarizes the main conclusions and recommendations from each section as well as the overall conclusions of the health risk assessment process. The terms used in this monograph to describe the strength of evidence for a given health outcome are as follows. Evidence is termed "limited" when it is restricted to a single study or when there are unresolved questions concerning the design, conduct or interpretation of a number of studies. "Inadequate" evidence is used when the studies cannot be interpreted as showing either the presence or absence of an effect because of major qualitative or quantitative limitations, or when no data are available.

Key gaps in knowledge were also identified and the research needed to fill these gaps has been summarized in the section entitled "Recommendations for research".

1.1 Summary

1.1.1 Sources, measurements and exposures

Electric and magnetic fields exist wherever electricity is generated, transmitted or distributed in power lines or cables, or used in electrical appliances. Since the use of electricity is an integral part of our modern lifestyle, these fields are ubiquitous in our environment.

The unit of electric field strength is volts per metre (V m⁻¹) or kilovolts per metre (kV m⁻¹) and for magnetic fields the flux density is measured in tesla (T), or more commonly in millitesla (mT) or microtesla (μ T) is used.

Residential exposure to power-frequency magnetic fields does not vary dramatically across the world. The geometric-mean magnetic field in homes ranges between 0.025 and 0.07 μT in Europe and 0.055 and 0.11 μT in the USA. The mean values of the electric field in the home are in the range of several tens of volts per metre. In the vicinity of certain appliances, the

instantaneous magnetic-field values can be as much as a few hundred microtesla. Near power lines, magnetic fields reach approximately 20 μT and electric fields up to several thousand volts per metre.

Few children have time-averaged exposures to residential 50 or 60 Hz magnetic fields in excess of the levels associated with an increased incidence of childhood leukaemia (see section 1.1.10). Approximately 1% to 4% have mean exposures above 0.3 μT and only 1% to 2% have median exposures in excess of 0.4 μT .

Occupational exposure, although predominantly to power-frequency fields, may also include contributions from other frequencies. The average magnetic field exposures in the workplace have been found to be higher in "electrical occupations" than in other occupations such as office work, ranging from 0.4–0.6 μT for electricians and electrical engineers to approximately 1.0 μT for power line workers, with the highest exposures for welders, railway engine drivers and sewing machine operators (above 3 μT). The maximum magnetic field exposures in the workplace can reach approximately 10 mT and this is invariably associated with the presence of conductors carrying high currents. In the electrical supply industry, workers may be exposed to electric fields up to 30 kV m $^{-1}$.

1.1.2 Electric and magnetic fields inside the body

Exposure to external electric and magnetic fields at extremely low frequencies induces electric fields and currents inside the body. Dosimetry describes the relationship between the external fields and the induced electric field and current density in the body, or other parameters associated with exposure to these fields. The locally induced electric field and current density are of particular interest because they relate to the stimulation of excitable tissue such as nerve and muscle.

The bodies of humans and animals significantly perturb the spatial distribution of an ELF electric field. At low frequencies the body is a good conductor and the perturbed field lines outside the body are nearly perpendicular to the body surface. Oscillating charges are induced on the surface of the exposed body and these induce currents inside the body. The key features of dosimetry for the exposure of humans to ELF electric fields are as follows:

- The electric field inside the body is normally five to six orders of magnitude smaller than the external electric field.
- When exposure is mostly to the vertical field, the predominant direction of the induced fields is also vertical.
- For a given external electric field, the strongest induced fields are for the human body in perfect contact through the feet with ground (electrically grounded) and the weakest induced fields are for the body insulated from the ground (in "free space").

- The total current flowing in a body in perfect contact with ground is determined by the body size and shape (including posture), rather than tissue conductivity.
- The distribution of induced currents across the various organs and tissues is determined by the conductivity of those tissues
- The distribution of an induced electric field is also affected by the conductivities, but less so than the induced current.
- There is also a separate phenomenon in which the current in the body is produced by means of contact with a conductive object located in an electric field.

For magnetic fields, the permeability of tissue is the same as that of air, so the field in tissue is the same as the external field. The bodies of humans and animals do not significantly perturb the field. The main interaction of magnetic fields is the Faraday induction of electric fields and associated current densities in the conductive tissues. The key features of dosimetry for the exposure of humans to ELF magnetic fields are as follows:

- The induced electric field and current depend on the orientation of the external field. Induced fields in the body as a whole are greatest when the field is aligned from the front to the back of the body, but for some individual organs the highest values are for the field aligned from side to side.
- The weakest electric fields are induced by a magnetic field oriented along the vertical body axis.
- For a given magnetic field strength and orientation, higher electric fields are induced in larger bodies.
- The distribution of the induced electric field is affected by the conductivity of the various organs and tissues. These have a limited effect on the distribution of induced current density.

1.1.3 Biophysical mechanisms

Various proposed direct and indirect interaction mechanisms for ELF electric and magnetic fields are examined for plausibility, in particular whether a "signal" generated in a biological process by exposure to a field can be discriminated from inherent random noise and whether the mechanism challenges scientific principles and current scientific knowledge. Many mechanisms become plausible only at fields above a certain strength. Nevertheless, the lack of identified plausible mechanisms does not rule out the possibility of health effects even at very low field levels, provided basic scientific principles are adhered to.

Of the numerous proposed mechanisms for the direct interaction of fields with the human body, three stand out as potentially operating at lower field levels than the others: induced electric fields in neural networks, radical pairs and magnetite.

Electric fields induced in tissue by exposure to ELF electric or magnetic fields will directly stimulate single myelinated nerve fibres in a biophysically plausible manner when the internal field strength exceeds a few volts per metre. Much weaker fields can affect synaptic transmission in neural networks as opposed to single cells. Such signal processing by nervous systems is commonly used by multicellular organisms to detect weak environmental signals. A lower bound on neural network discrimination of 1 mV m⁻¹ has been suggested, but based on current evidence, threshold values around 10–100 mV m⁻¹ seem to be more likely.

The radical pair mechanism is an accepted way in which magnetic fields can affect specific types of chemical reactions, generally increasing concentrations of reactive free radicals in low fields and decreasing them in high fields. These increases have been seen in magnetic fields of less than 1 mT. There is some evidence linking this mechanism to navigation during bird migration. Both on theoretical grounds and because the changes produced by ELF and static magnetic fields are similar, it is suggested that power-frequency fields of much less than the geomagnetic field of around 50 μT are unlikely to be of much biological significance.

Magnetite crystals, small ferromagnetic crystals of various forms of iron oxide, are found in animal and human tissues, although in trace amounts. Like free radicals, they have been linked to orientation and navigation in migratory animals, although the presence of trace quantities of magnetite in the human brain does not confer an ability to detect the weak geomagnetic field. Calculations based on extreme assumptions suggest a lower bound for the effects on magnetite crystals of ELF fields of 5 μT .

Other direct biophysical interactions of fields, such as the breaking of chemical bonds, the forces on charged particles and the various narrow bandwidth "resonance" mechanisms, are not considered to provide plausible explanations for the interactions at field levels encountered in public and occupational environments.

With regard to indirect effects, the surface electric charge induced by electric fields can be perceived, and it can result in painful microshocks when touching a conductive object. Contact currents can occur when young children touch, for example, a tap in the bathtub in some homes. This produces small electric fields, possibly above background noise levels, in bone marrow. However, whether these present a risk to health is unknown.

High-voltage power lines produce clouds of electrically charged ions as a consequence of corona discharge. It is suggested that they could increase the deposition of airborne pollutants on the skin and on airways inside the body, possibly adversely affecting health. However, it seems unlikely that corona ions will have more than a small effect, if any, on long-term health risks, even in the individuals who are most exposed.

None of the three direct mechanisms considered above seem plausible causes of increased disease incidence at the exposure levels generally encountered by people. In fact they only become plausible at levels orders of

magnitude higher and indirect mechanisms have not yet been sufficiently investigated. This absence of an identified plausible mechanism does not rule out the possibility of adverse health effects, but it does create a need for stronger evidence from biology and epidemiology.

1.1.4 Neurobehaviour

Exposure to power-frequency electric fields causes well-defined biological responses, ranging from perception to annoyance, through surface electric charge effects. These responses depend on the field strength, the ambient environmental conditions and individual sensitivity. The thresholds for direct perception by 10% of volunteers varied between 2 and 20 kV m⁻¹, while 5% found 15–20 kV m⁻¹ annoying. The spark discharge from a person to ground is found to be painful by 7% of volunteers in a field of 5 kV m⁻¹. Thresholds for the discharge from a charged object through a grounded person depend on the size of the object and therefore require specific assessment.

High field strength, rapidly pulsed magnetic fields can stimulate peripheral or central nerve tissue; such effects can arise during magnetic resonance imaging (MRI) procedures, and are used in transcranial magnetic stimulation. Threshold induced electric field strengths for direct nerve stimulation could be as low as a few volts per metre. The threshold is likely to be constant over a frequency range between a few hertz and a few kilohertz. People suffering from or predisposed to epilepsy are likely to be more susceptible to induced ELF electric fields in the central nervous system (CNS). Furthermore, sensitivity to electrical stimulation of the CNS seems likely to be associated with a family history of seizure and the use of tricyclic antidepressants, neuroleptic agents and other drugs that lower the seizure threshold.

The function of the retina, which is a part of the CNS, can be affected by exposure to much weaker ELF magnetic fields than those that cause direct nerve stimulation. A flickering light sensation, called magnetic phosphenes or magnetophosphenes, results from the interaction of the induced electric field with electrically excitable cells in the retina. Threshold induced electric field strengths in the extracellular fluid of the retina have been estimated to lie between about 10 and 100 mV m⁻¹ at 20 Hz. There is, however, considerable uncertainty attached to these values.

The evidence for other neurobehavioural effects in volunteer studies, such as the effects on brain electrical activity, cognition, sleep, hypersensitivity and mood, is less clear. Generally, such studies have been carried out at exposure levels below those required to induce the effects described above, and have produced evidence only of subtle and transitory effects at best. The conditions necessary to elicit such responses are not well-defined at present. There is some evidence suggesting the existence of field-dependent effects on reaction time and on reduced accuracy in the performance of some cognitive tasks, which is supported by the results of studies on the gross electrical activity of the brain. Studies investigating whether magnetic fields affect sleep quality have reported inconsistent results. It is possible that these

inconsistencies may be attributable in part to differences in the design of the studies.

Some people claim to be hypersensitive to EMFs in general. However, the evidence from double-blind provocation studies suggests that the reported symptoms are unrelated to EMF exposure.

There is only inconsistent and inconclusive evidence that exposure to ELF electric and magnetic fields causes depressive symptoms or suicide. Thus, the evidence is considered inadequate.

In animals, the possibility that exposure to ELF fields may affect neurobehavioural functions has been explored from a number of perspectives using a range of exposure conditions. Few robust effects have been established. There is convincing evidence that power-frequency electric fields can be detected by animals, most likely as a result of surface charge effects, and may elicit transient arousal or mild stress. In rats, the detection range is between 3 and 13 kV m⁻¹. Rodents have been shown to be aversive to field strengths greater than 50 kV m⁻¹. Other possible field-dependent changes are less well-defined; laboratory studies have only produced evidence of subtle and transitory effects. There is some evidence that exposure to magnetic fields may modulate the functions of the opioid and cholinergic neurotransmitter systems in the brain, and this is supported by the results of studies investigating the effects on analgesia and on the acquisition and performance of spatial memory tasks.

1.1.5 Neuroendocrine system

The results of volunteer studies as well as residential and occupational epidemiological studies suggest that the neuroendocrine system is not adversely affected by exposure to power-frequency electric or magnetic fields. This applies particularly to the circulating levels of specific hormones of the neuroendocrine system, including melatonin, released by the pineal gland, and to a number of hormones involved in the control of body metabolism and physiology, released by the pituitary gland. Subtle differences were sometimes observed in the timing of melatonin release associated with certain characteristics of exposure, but these results were not consistent. It is very difficult to eliminate possible confounding by a variety of environmental and lifestyle factors that might also affect hormone levels. Most laboratory studies of the effects of ELF exposure on night-time melatonin levels in volunteers found no effect when care was taken to control possible confounding.

From the large number of animal studies investigating the effects of power-frequency electric and magnetic fields on rat pineal and serum melatonin levels, some reported that exposure resulted in night-time suppression of melatonin. The changes in melatonin levels first observed in early studies of electric field exposures up to 100 kV m⁻¹ could not be replicated. The findings from a series of more recent studies, which showed that circularly-polarised magnetic fields suppressed night-time melatonin levels, were weakened by inappropriate comparisons between exposed animals and his-

torical controls. The data from other experiments in rodents, covering intensity levels from a few microtesla to 5 mT, were equivocal, with some results showing depression of melatonin, but others showing no changes. In seasonally breeding animals, the evidence for an effect of exposure to power-frequency fields on melatonin levels and melatonin-dependent reproductive status is predominantly negative. No convincing effect on melatonin levels has been seen in a study of non-human primates chronically exposed to power-frequency fields, although a preliminary study using two animals reported melatonin suppression in response to an irregular and intermittent exposure.

The effects of exposure to ELF fields on melatonin production or release in isolated pineal glands were variable, although relatively few in vitro studies have been undertaken. The evidence that ELF exposure interferes with the action of melatonin on breast cancer cells in vitro is intriguing. However this system suffers from the disadvantage that the cell lines frequently show genotypic and phenotypic drift in culture that can hinder transferability between laboratories.

No consistent effects have been seen in the stress-related hormones of the pituitary-adrenal axis in a variety of mammalian species, with the possible exception of short-lived stress following the onset of ELF electric field exposure at levels high enough to be perceived. Similarly, while few studies have been carried out, mostly negative or inconsistent effects have been observed in the levels of growth hormone and of hormones involved in controlling metabolic activity or associated with the control of reproduction and sexual development.

Overall, these data do not indicate that ELF electric and/or magnetic fields affect the neuroendocrine system in a way that would have an adverse impact on human health and the evidence is thus considered inadequate.

1.1.6 Neurodegenerative disorders

It has been hypothesized that exposure to ELF fields is associated with several neurodegenerative diseases. For Parkinson disease and multiple sclerosis the number of studies has been small and there is no evidence for an association with these diseases. For Alzheimer disease and amyotrophic lateral sclerosis (ALS) more studies have been published. Some of these reports suggest that people employed in electrical occupations might have an increased risk of ALS. So far, no biological mechanism has been established which can explain this association, although it could have arisen because of confounders related to electrical occupations, such as electric shocks. Overall, the evidence for the association between ELF exposure and ALS is considered to be inadequate.

The few studies investigating the association between ELF exposure and Alzheimer disease are inconsistent. However, the higher quality studies that focused on Alzheimer morbidity rather than mortality do not

indicate an association. Altogether, the evidence for an association between ELF exposure and Alzheimer disease is inadequate.

1.1.7 Cardiovascular disorders

Experimental studies of both short-term and long-term exposure indicate that while electric shock is an obvious health hazard, other hazard-ous cardiovascular effects associated with ELF fields are unlikely to occur at exposure levels commonly encountered environmentally or occupationally. Although various cardiovascular changes have been reported in the literature, the majority of effects are small and the results have not been consistent within and between studies. With one exception, none of the studies of cardiovascular disease morbidity and mortality has shown an association with exposure. Whether a specific association exists between exposure and altered autonomic control of the heart remains speculative. Overall, the evidence does not support an association between ELF exposure and cardiovascular disease.

1.1.8 Immunology and haematology

Evidence for the effects of ELF electric or magnetic fields on components of the immune system is generally inconsistent. Many of the cell populations and functional markers were unaffected by exposure. However, in some human studies with fields from 10 μT to 2 mT, changes were observed in natural killer cells, which showed both increased and decreased cell numbers, and in total white blood cell counts, which showed no change or decreased numbers. In animal studies, reduced natural killer cell activity was seen in female mice, but not in male mice or in rats of either sex. White blood cell counts also showed inconsistency, with decreases or no change reported in different studies. The animal exposures had an even broader range of 2 μT to 30 mT. The difficulty in interpreting the potential health impact of these data is due to the large variations in exposure and environmental conditions, the relatively small numbers of subjects tested and the broad range of endpoints.

There have been few studies carried out on the effects of ELF magnetic fields on the haematological system. In experiments evaluating differential white blood cell counts, exposures ranged from 2 μT to 2 mT. No consistent effects of acute exposure to ELF magnetic fields or to combined ELF electric and magnetic fields have been found in either human or animal studies

Overall therefore, the evidence for effects of ELF electric or magnetic fields on the immune and haematological system is considered inadequate.

1.1.9 Reproduction and development

On the whole, epidemiological studies have not shown an association between adverse human reproductive outcomes and maternal or paternal exposure to ELF fields. There is some evidence for an increased risk of mis-

carriage associated with maternal magnetic field exposure, but this evidence is inadequate.

Exposures to ELF electric fields of up to 150 kV m⁻¹ have been evaluated in several mammalian species, including studies with large group sizes and exposure over several generations. The results consistently show no adverse developmental effects.

The exposure of mammals to ELF magnetic fields of up to 20 mT does not result in gross external, visceral or skeletal malformations. Some studies show an increase in minor skeletal anomalies, in both rats and mice. Skeletal variations are relatively common findings in teratological studies and are often considered biologically insignificant. However, subtle effects of magnetic fields on skeletal development cannot be ruled out. Very few studies have been published which address reproductive effects and no conclusions can be drawn from them.

Several studies on non-mammalian experimental models (chick embryos, fish, sea urchins and insects) have reported findings indicating that ELF magnetic fields at microtesla levels may disturb early development. However, the findings of non-mammalian experimental models carry less weight in the overall evaluation of developmental toxicity than those of corresponding mammalian studies.

Overall, the evidence for developmental and reproductive effects is inadequate.

1.1.10 Cancer

The IARC classification of ELF magnetic fields as "possibly carcinogenic to humans" (IARC, 2002) is based upon all of the available data prior to and including 2001. The review of literature in this EHC monograph focuses mainly on studies published after the IARC review.

Epidemiology

The IARC classification was heavily influenced by the associations observed in epidemiological studies on childhood leukaemia. The classification of this evidence as limited does not change with the addition of two childhood leukaemia studies published after 2002. Since the publication of the IARC monograph the evidence for other childhood cancers remains inadequate.

Subsequent to the IARC monograph a number of reports have been published concerning the risk of female breast cancer in adults associated with ELF magnetic field exposure. These studies are larger than the previous ones and less susceptible to bias, and overall are negative. With these studies, the evidence for an association between ELF magnetic field exposure and the risk of female breast cancer is weakened considerably and does not support an association of this kind.

In the case of adult brain cancer and leukaemia, the new studies

published after the IARC monograph do not change the conclusion that the overall evidence for an association between ELF magnetic fields and the risk of these diseases remains inadequate.

For other diseases and all other cancers, the evidence remains inadequate.

Laboratory animal studies

There is currently no adequate animal model of the most common form of childhood leukaemia, acute lymphoblastic leukaemia. Three independent large-scale studies of rats provided no evidence of an effect of ELF magnetic fields on the incidence of spontaneous mammary tumours. Most studies report no effect of ELF magnetic fields on leukaemia or lymphoma in rodent models. Several large-scale long-term studies in rodents have not shown any consistent increase in any type of cancer, including haematopoietic, mammary, brain and skin tumours.

A substantial number of studies have examined the effects of ELF magnetic fields on chemically-induced mammary tumours in rats. Inconsistent results were obtained that may be due in whole or in part to differences in experimental protocols, such as the use of specific sub-strains. Most studies on the effects of ELF magnetic field exposure on chemically-induced or radiation-induced leukaemia/lymphoma models were negative. Studies of pre-neoplastic liver lesions, chemically-induced skin tumours and brain tumours reported predominantly negative results. One study reported an acceleration of UV-induced skin tumourigenesis upon exposure to ELF magnetic fields.

Two groups have reported increased levels of DNA strand breaks in brain tissue following in vivo exposure to ELF magnetic fields. However, other groups, using a variety of different rodent genotoxicity models, found no evidence of genotoxic effects. The results of studies investigating nongenotoxic effects relevant to cancer are inconclusive.

Overall there is no evidence that exposure to ELF magnetic fields alone causes tumours. The evidence that ELF magnetic field exposure can enhance tumour development in combination with carcinogens is inadequate.

In vitro studies

Generally, studies of the effects of ELF field exposure of cells have shown no induction of genotoxicity at fields below 50 mT. The notable exception is evidence from recent studies reporting DNA damage at field strengths as low as 35 $\mu T_{\rm i}$ however, these studies are still being evaluated and our understanding of these findings is incomplete. There is also increasing evidence that ELF magnetic fields may interact with DNA-damaging agents.

There is no clear evidence of the activation by ELF magnetic fields of genes associated with the control of the cell cycle. However, systematic studies analysing the response of the whole genome have yet to be performed

Many other cellular studies, for example on cell proliferation, apoptosis, calcium signalling and malignant transformation, have produced inconsistent or inconclusive results.

Overall conclusion

New human, animal and in vitro studies, published since the 2002 IARC monograph, do not change the overall classification of ELF magnetic fields as a possible human carcinogen.

1.1.11 Health risk assessment

According to the WHO Constitution, health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. A risk assessment is a conceptual framework for a structured review of information relevant to estimating health or environmental outcomes. The health risk assessment can be used as an input to risk management that encompasses all the activities needed to reach decisions on whether an exposure requires any specific action(s) and the undertaking of these actions.

In the evaluation of human health risks, sound human data, whenever available, are generally more informative than animal data. Animal and in vitro studies can support evidence from human studies, fill data gaps left in the evidence from human studies or be used to make a decision about risks when human studies are inadequate or absent.

All studies, with either positive or negative effects, need to be evaluated and judged on their own merit and then all together in a weight-of-evidence approach. It is important to determine to what extent a set of evidence changes the probability that exposure causes an outcome. The evidence for an effect is generally strengthened if the results from different types of studies (epidemiology and laboratory) point to the same conclusion and/or when multiple studies of the same type show the same result.

Acute effects

Acute biological effects have been established for exposure to ELF electric and magnetic fields in the frequency range up to 100 kHz that may have adverse consequences on health. Therefore, exposure limits are needed. International guidelines exist that have addressed this issue. Compliance with these guidelines provides adequate protection for acute effects.

Chronic effects

Scientific evidence suggesting that everyday, chronic low-intensity (above $0.3{\text -}0.4~\mu\text{T}$) power-frequency magnetic field exposure poses a health

risk is based on epidemiological studies demonstrating a consistent pattern of increased risk for childhood leukaemia. Uncertainties in the hazard assessment include the role that control selection bias and exposure misclassification might have on the observed relationship between magnetic fields and childhood leukaemia. In addition, virtually all of the laboratory evidence and the mechanistic evidence fail to support a relationship between low-level ELF magnetic fields and changes in biological function or disease status. Thus, on balance, the evidence is not strong enough to be considered causal, but sufficiently strong to remain a concern.

Although a causal relationship between magnetic field exposure and childhood leukaemia has not been established, the possible public health impact has been calculated assuming causality in order to provide a potentially useful input into policy. However, these calculations are highly dependent on the exposure distributions and other assumptions, and are therefore very imprecise. Assuming that the association is causal, the number of cases of childhood leukaemia worldwide that might be attributable to exposure can be estimated to range from 100 to 2400 cases per year. However, this represents 0.2 to 4.9% of the total annual incidence of leukaemia cases, estimated to be 49 000 worldwide in 2000. Thus, in a global context, the impact on public health, if any, would be limited and uncertain.

A number of other diseases have been investigated for possible association with ELF magnetic field exposure. These include cancers in both children and adults, depression, suicide, reproductive dysfunction, developmental disorders, immunological modifications and neurological disease. The scientific evidence supporting a linkage between ELF magnetic fields and any of these diseases is much weaker than for childhood leukaemia and in some cases (for example, for cardiovascular disease or breast cancer) the evidence is sufficient to give confidence that magnetic fields do not cause the disease.

1.1.12 Protective measures

It is essential that exposure limits be implemented in order to protect against the established adverse effects of exposure to ELF electric and magnetic fields. These exposure limits should be based on a thorough examination of all the relevant scientific evidence.

Only the acute effects have been established and there are two international exposure limit guidelines (ICNIRP, 1998a; IEEE, 2002) designed to protect against these effects.

As well as these established acute effects, there are uncertainties about the existence of chronic effects, because of the limited evidence for a link between exposure to ELF magnetic fields and childhood leukaemia. Therefore the use of precautionary approaches is warranted. However, it is not recommended that the limit values in exposure guidelines be reduced to some arbitrary level in the name of precaution. Such practice undermines the scientific foundation on which the limits are based and is likely to be an expensive and not necessarily effective way of providing protection.

Implementing other suitable precautionary procedures to reduce exposure is reasonable and warranted. However, electric power brings obvious health, social and economic benefits, and precautionary approaches should not compromise these benefits. Furthermore, given both the weakness of the evidence for a link between exposure to ELF magnetic fields and childhood leukaemia, and the limited impact on public health if there is a link, the benefits of exposure reduction on health are unclear. Thus the costs of precautionary measures should be very low. The costs of implementing exposure reductions will vary from one country to another, making it very difficult to provide a general recommendation for balancing the costs against the potential risk from ELF fields.

In view of the above, the following recommendations are given.

- Policy-makers should establish guidelines for ELF field exposure for both the general public and workers. The best source of guidance for both exposure levels and the principles of scientific review are the international guidelines.
- Policy-makers should establish an ELF EMF protection programme that includes measurements of fields from all sources to ensure that the exposure limits are not exceeded either for the general public or workers.
- Provided that the health, social and economic benefits of electric power are not compromised, implementing very low-cost precautionary procedures to reduce exposure is reasonable and warranted.
- Policy-makers, community planners and manufacturers should implement very low-cost measures when constructing new facilities and designing new equipment including appliances.
- Changes to engineering practice to reduce ELF exposure from equipment or devices should be considered, provided that they yield other additional benefits, such as greater safety, or little or no cost.
- When changes to existing ELF sources are contemplated, ELF field reduction should be considered alongside safety, reliability and economic aspects.
- Local authorities should enforce wiring regulations to reduce unintentional ground currents when building new or rewiring existing facilities, while maintaining safety. Proactive measures to identify violations or existing problems in wiring would be expensive and unlikely to be justified.
- National authorities should implement an effective and open communication strategy to enable informed decision-making by all stakeholders; this should include information on how individuals can reduce their own exposure.

- Local authorities should improve planning of ELF EMF-emitting facilities, including better consultation between industry, local government, and citizens when siting major ELF EMF-emitting sources.
- Government and industry should promote research programmes to reduce the uncertainty of the scientific evidence on the health effects of ELF field exposure.

1.2 Recommendations for research

Identifying the gaps in the knowledge concerning the possible health effects of exposure to ELF fields is an essential part of this health risk assessment. This has resulted in the following recommendations for further research (summarized in Table 1).

As an overarching need, further research on intermediate frequencies (IF), usually taken as frequencies between 300 Hz and 100 kHz, is required, given the present lack of data in this area. Very little of the required knowledge base for a health risk assessment has been gathered and most existing studies have contributed inconsistent results, which need to be further substantiated. General requirements for constituting a sufficient IF database for health risk assessment include exposure assessment, epidemiological and human laboratory studies, and animal and cellular (in vitro) studies (ICNIRP, 2003; ICNIRP, 2004; Litvak, Foster & Repacholi, 2002).

For all volunteer studies, it is mandatory that research on human subjects is conducted in full accord with ethical principles, including the provisions of the Helsinki Declaration (WMA, 2004).

For laboratory studies, priority should be given to reported responses (i) for which there is at least some evidence of replication or confirmation, (ii) that are potentially relevant to carcinogenesis (for example, genotoxicity), (iii) that are strong enough to allow mechanistic analysis and (iv) that occur in mammalian or human systems.

1.2.1 Sources, measurements and exposures

The further characterization of homes with high ELF exposure in different countries to identify relative contributions of internal and external sources, the influence of wiring/grounding practices and other characteristics of the home could give insights into identifying a relevant exposure metric for epidemiological assessment. An important component of this is a better understanding of foetal and childhood exposure to ELF fields, especially from residential exposure to underfloor electrical heating and from transformers in apartment buildings.

It is suspected that in some cases of occupational exposure the present ELF guideline limits are exceeded. More information is needed on exposure (including to non-power frequencies) related to work on, for example, live-line maintenance, work within or near the bore of MRI magnets

(and hence to gradient-switching ELF fields) and work on transportation systems. Similarly, additional knowledge is needed about general public exposure which could come close to guideline limits, including sources such as security systems, library degaussing systems, induction cooking and water heating appliances.

Exposure to contact currents has been proposed as a possible explanation for the association of ELF magnetic fields with childhood leukaemia. Research is needed in countries other than the USA to assess the capability of residential electrical grounding and plumbing practices to give rise to contact currents in the home. Such studies would have priority in countries with important epidemiological results with respect to ELF and childhood leukaemia.

1.2.2 Dosimetry

In the past, most laboratory research was based on induced electric currents in the body as a basic metric and thus dosimetry was focused on this quantity. Only recently has work begun on exploring the relationship between external exposure and induced electric fields. For a better understanding of biological effects, more data on internal electric fields for different exposure conditions are needed.

Computation should be carried out of internal electric fields due to the combined influence of external electric and magnetic fields in different configurations. The vectorial addition of out-of-phase and spatially varying contributions of electric and magnetic fields is necessary to assess basic restriction compliance issues.

Very little computation has been carried out on advanced models of the pregnant woman and the foetus with appropriate anatomical modelling. It is important to assess possible enhanced induction of electric fields in the foetus in relation to the childhood leukaemia issue. Both maternal occupational and residential exposures are relevant here.

There is a need to further refine micro-dosimetric models in order to take into account the cellular architecture of neural networks and other complex suborgan systems identified as being more sensitive to induced electric field effects. This modelling process also needs to consider influences in cell membrane electrical potentials and on the release of neurotransmitters.

1.2.3 Biophysical mechanisms

There are three main areas where there are obvious limits to the current understanding of mechanisms: the radical pair mechanism, magnetic particles in the body and signal-to-noise ratios in multicell systems, such as neuronal networks.

The radical pair mechanism is one of the more plausible low-level interaction mechanisms, but it has yet to be shown that it is able to mediate significant effects in cell metabolism and function. It is particularly impor-

tant to understand the lower limit of exposure at which it acts, so as to judge whether this could or could not be a relevant mechanism for carcinogenesis. Given recent studies in which reactive oxygen species were increased in immune cells exposed to ELF fields, it is recommended that cells from the immune system that generate reactive oxygen species as part of their immune response be used as cellular models for investigating the potential of the radical pair mechanism.

Although the presence of magnetic particles (magnetite crystals) in the human brain does not, on present evidence, appear to confer a sensitivity to environmental ELF magnetic fields, further theoretical and experimental approaches should explore whether such sensitivity could exist under certain conditions. Moreover, any modification that the presence of magnetite might have on the radical pair mechanism discussed above should be pursued.

The extent to which multicell mechanisms operate in the brain so as to improve signal-to-noise ratios should be further investigated in order to develop a theoretical framework for quantifying this or for determining any limits on it. Further investigation of the threshold and frequency response of the neuronal networks in the hippocampus and other parts of the brain should be carried out using in vitro approaches.

1.2.4 Neurobehaviour

It is recommended that laboratory-based volunteer studies on the possible effects on sleep and on the performance of mentally demanding tasks be carried out using harmonized methodological procedures. There is a need to identify dose-response relationships at higher magnetic flux densities than used previously and a wide range of frequencies (i.e. in the kilohertz range).

Studies of adult volunteers and animals suggest that acute cognitive effects may occur with short-term exposures to intense electric or magnetic fields. The characterization of such effects is very important for the development of exposure guidance, but there is a lack of specific data concerning field-dependent effects in children. The implementation of laboratory-based studies of cognition and changes in electroencephalograms (EEGs) in people exposed to ELF fields is recommended, including adults regularly subjected to occupational exposure and children.

Behavioural studies on immature animals provide a useful indicator of the possible cognitive effects on children. The possible effects of pre- and postnatal exposure to ELF magnetic fields on the development of the nervous system and cognitive function should be studied. These studies could be usefully supplemented by investigations into the effects of exposure to ELF magnetic fields and induced electric fields on nerve cell growth using brain slices or cultured neurons.

There is a need to further investigate potential health consequences suggested by experimental data showing opioid and cholinergic responses in animals. Studies examining the modulation of opioid and cholinergic

responses in animals should be extended and the exposure parameters and the biological basis for these behavioural responses should be defined.

1.2.5 Neuroendocrine system

The existing database of neuroendocrine response does not indicate that ELF exposure would have adverse impacts on human health. Therefore no recommendations for additional research are given.

1.2.6 Neurodegenerative disorders

Several studies have observed an increased risk of amyotrophic lateral sclerosis in "electrical occupations". It is considered important to investigate this association further in order to discover whether ELF magnetic fields are involved in the causation of this rare neurodegenerative disease. This research requires large prospective cohort studies with information on ELF magnetic field exposure, electric shock exposure as well as exposure to other potential risk factors.

It remains questionable whether ELF magnetic fields constitute a risk factor for Alzheimer's disease. The data currently available are not sufficient and this association should be further investigated. Of particular importance is the use of morbidity rather than mortality data.

1.2.7 Cardiovascular disorders

Further research into the association between ELF magnetic fields and the risk of cardiovascular disease is not considered a priority.

1.2.8 Immunology and haematology

Changes observed in immune and haematological parameters in adults exposed to ELF magnetic fields showed inconsistencies, and there are essentially no research data available for children. Therefore, the recommendation is to conduct studies on the effects of ELF exposure on the development of the immune and haematopoietic systems in juvenile animals.

1.2.9 Reproduction and development

There is some evidence of an increased risk of miscarriage associated with ELF magnetic field exposure. Taking into account the potentially high public health impact of such an association, further epidemiological research is recommended.

1.2.10 Cancer

Resolving the conflict between epidemiological data (which show an association between ELF magnetic field exposure and an increased risk of childhood leukaemia) and experimental and mechanistic data (which do not support this association) is the highest research priority in this field. It is recommended that epidemiologists and experimental scientists collaborate on this. For new epidemiological studies to be informative they must focus on new aspects of exposure, potential interaction with other factors or on high exposure groups, or otherwise be innovative in this area of research. In addi-

tion, it is also recommended that the existing pooled analyses be updated, by adding data from recent studies and by applying new insights into the analysis.

Childhood brain cancer studies have shown inconsistent results. As with childhood leukaemia, a pooled analysis of childhood brain cancer studies should be very informative and is therefore recommended. A pooled analysis of this kind can inexpensively provide a greater and improved insight into the existing data, including the possibility of selection bias and, if the studies are sufficiently homogeneous, can offer the best estimate of risk.

For adult breast cancer more recent studies have convincingly shown no association with exposure to ELF magnetic fields. Therefore further research into this association should be given very low priority.

For adult leukaemia and brain cancer the recommendation is to update the existing large cohorts of occupationally exposed individuals. Occupational studies, pooled analyses and meta-analyses for leukaemia and brain cancer have been inconsistent and inconclusive. However, new data have subsequently been published and should be used to update these analyses.

The priority is to address the epidemiological evidence by establishing appropriate in vitro and animal models for responses to low-level ELF magnetic fields that are widely transferable between laboratories.

Transgenic rodent models for childhood leukaemia should be developed in order to provide appropriate experimental animal models to study the effect of ELF magnetic field exposure. Otherwise, for existing animal studies, the weight of evidence is that there are no carcinogenic effects of ELF magnetic fields alone. Therefore high priority should be given to in vitro and animal studies in which ELF magnetic fields are rigorously evaluated as a co-carcinogen.

With regard to other in vitro studies, experiments reporting the genotoxic effects of intermittent ELF magnetic field exposure should be replicated

1.2.11 Protective measures

Research on the development of health protection policies and policy implementation in areas of scientific uncertainty is recommended, specifically on the use of precaution, the interpretation of precaution and the evaluation of the impact of precautionary measures for ELF magnetic fields and other agents classified as "possible human carcinogens". Where there are uncertainties about the potential health risk an agent poses for society, precautionary measures may be warranted in order to ensure the appropriate protection of the public and workers. Only limited research has been performed on this issue for ELF magnetic fields and because of its importance, more research is needed. This may help countries to integrate precaution into their health protection policies.

Further research on risk perception and communication which is specifically focused on electromagnetic fields is advised. Psychological and sociological factors that influence risk perception in general have been widely investigated. However, limited research has been carried out to analyse the relative importance of these factors in the case of electromagnetic fields or to identify other factors that are specific to electromagnetic fields. Recent studies have suggested that precautionary measures which convey implicit risk messages can modify risk perception by either increasing or reducing concerns. Deeper investigation in this area is therefore warranted.

Research on the development of a cost-benefit/cost-effectiveness analysis for the mitigation of ELF magnetic fields should be carried out. The use of cost-benefit and cost-effectiveness analyses for evaluating whether a policy option is beneficial to society has been researched in many areas of public policy. The development of a framework that will identify which parameters are necessary in order to perform this analysis for ELF magnetic fields is needed. Due to uncertainties in the evaluation, quantifiable and unquantifiable parameters will need to be incorporated.

Sour	ces, measurements and exposures	Priority
Jour	ces, measurements and exposures	FIIOTILY
	Further characterization of homes with high ELF magnetic field exposure in different countries	Medium
	Identify gaps in knowledge about occupational ELF exposure, such as in MRI	High
	Assess the ability of residential wiring outside the USA to induce contact currents in children	Medium
Dosir	netry	
	Further computational dosimetry relating external electric and magnetic fields to internal electric fields, particularly concerning exposure to combined electric and magnetic fields in different orientations	Medium
	Calculation of induced electric fields and currents in pregnant women and in the foetus	Medium
	Further refinement of microdosimetric models taking into account the cellular architecture of neural networks and other complex suborgan systems	Medium
Biopl	nysical mechanisms	
	Further study of radical pair mechanisms in immune cells that generate reactive oxygen species as part of their phenotypic function	Medium
	Further theoretical and experimental study of the possible role of magnetite in ELF magnetic field sensitivity	Low
	Determination of threshold responses to internal electric fields induced by ELFs on multicell systems, such as neural networks, using theoretical and in vitro approaches	High

12 HEALTH RISK ASSESSMENT

12.1 Introduction

The control of health risks from the exposure to any physical, chemical or biological agent is informed by a scientific, ideally quantitative, assessment of potential effects at given exposure levels (risk assessment). Based upon the results of the risk assessment and taking into consideration other factors, a decision-making process aimed at eliminating or, if this is not possible, reducing to a minimum the risk from the agent (risk management) can be started. The discussion below is based on the WHO Environmental Health Criteria 210 which describes the principles for the assessment of risks to human health from exposure to chemicals (WHO, 1999). These principles are generally applicable and have been used here for ELF electric and magnetic fields

Risk assessment is a conceptual framework that provides the mechanism for a structured review of information relevant to estimating health or the environmental effects of exposure. The risk assessment process is divided into four distinct steps: hazard identification, exposure assessment, exposure-response assessment and risk characterization.

- The purpose of *hazard identification* is to evaluate qualitatively the weight of evidence for adverse effects in humans based on the assessment of all the available data on toxicity and modes of action. Primarily two questions are addressed: (1) whether ELF fields may pose a health hazard to human beings and (2) under what circumstances an identified hazard may occur. Hazard identification is based on analyses of a variety of data that may range from observations in humans to studies conducted in laboratories, as well as possible mechanisms of action.
- Exposure assessment is the determination of the nature and extent of exposure to EMF under different conditions. Multiple approaches can be used to conduct exposure assessments. These include direct techniques, such as the measurement of ambient and personal exposures, and indirect methods, for example questionnaires and computational techniques.
- Exposure-response assessment is the process of quantitatively characterizing the relationship between the exposure received and the occurrence of an effect. For most types of possible adverse effects (i.e. neurological, behavioural, immunological, reproductive or developmental effects), it is generally considered that there is an EMF exposure level below which adverse effects will not occur (i.e. a threshold). However, for other effects such as cancer, there may not be a threshold.
- Risk characterization is the final step in the risk assessment process. Its purpose is to support risk managers by providing the essential scientific evidence and rationale about risk that they need

for decision-making. In risk characterization, estimates of the risk to human health under relevant exposure scenarios are provided. Thus, a risk characterization is an evaluation and integration of the available scientific evidence and is used to estimate the nature, importance and often the magnitude of human risk, including a recognition and characterization of uncertainty that can reasonably be estimated to result from exposure to EMF under specific circumstances

The health risk assessment can be used as an input to risk management, which encompasses (1) all the activities needed to reach decisions on whether an exposure requires any specific action(s), (2) which actions are appropriate and (3) the undertaking of these actions. Such risk management activities are further discussed in Chapter 13.

12.2 Hazard identification

12.2.1 Biological versus adverse health effects

According to the WHO Constitution, health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. Before identifying any actual health hazards, it is useful to clarify the difference between a biological effect and an adverse health effect. A biological effect is any physiological response to, in this case, exposure to ELF fields. Some biological effects may have no influence on health, some may have beneficial consequences, while others may result in pathological conditions, i.e. adverse health effects. Annoyance or discomfort caused by ELF exposure may not be pathological per se but, if substantiated, can affect the physical and mental well-being of a person and the resultant effect may be considered to be an adverse health effect.

12.2.2 Acute effects

ELF electric and magnetic fields can affect the nervous systems of people exposed to them, resulting in adverse health consequences such as nerve stimulation, at very high exposure levels. Exposure at lower levels induces changes in the excitability of nervous tissue in the central nervous system which may affect memory, cognition and other brain functions. These acute effects on the nervous system form the basis of international guidelines. However, they are unlikely to occur at the low exposure levels in the general environment and most working environments.

Exposure to ELF electric fields also induces a surface electric charge which can lead to perceptible, but non-hazardous effects, including microshocks.

12.2.3 Chronic effects

Scientific evidence suggesting that everyday, chronic, low-intensity ELF magnetic field exposure poses a possible health risk is based on epidemiological studies demonstrating a consistent pattern of an increased risk of childhood leukaemia. Uncertainties in the hazard assessment include the role

of control selection bias and exposure misclassification. In addition, virtually all of the laboratory evidence and the mechanistic evidence fails to support a relationship between low-level ELF magnetic field exposure and changes in biological function or disease status. Thus, on balance, the evidence is not strong enough to be considered causal and therefore ELF magnetic fields remain classified as possibly carcinogenic.

A number of other diseases have been investigated for possible association with ELF magnetic field exposure. These include other types of cancers in both children and adults, depression, suicide, reproductive dysfunction, developmental disorders, immunological modifications, neurological disease and cardiovascular disease. The scientific evidence supporting a linkage between exposure to ELF magnetic fields and any of these diseases is weaker than for childhood leukaemia and in some cases (for example, for cardiovascular disease or breast cancer) the evidence is sufficient to give confidence that magnetic fields do not cause the disease.

12.3 Exposure assessment

Electric and magnetic field exposures can be expressed in terms of instantaneous or temporally averaged values. Either of these can be calculated from source parameters or measured.

12.3.1 Residential exposures

In the case of residential exposure, data from various countries show that the geometric means of ELF magnetic field strengths across homes do not vary dramatically. Mean values of ELF electric fields in the home can be up to several tens of volts per metre. In the vicinity of some appliances, the instantaneous magnetic field values can be as much as a few hundreds of microtesla. Close to power lines, magnetic fields reach as much as approximately $20~\mu T$ and electric fields can be between several hundreds and several thousands of volts per metre.

The epidemiological studies on childhood leukaemia have focused on average residential ELF magnetic fields above 0.3 to 0.4 μT as a risk factor for cancer. Results from several extensive surveys showed that approximately 0.5–7% of children had time-averaged exposures in excess of 0.3 μT and 0.4–3.3% were exposed to in excess of 0.4 μT . Calculations based on case-control studies of ELF magnetic field exposure and childhood leukaemia resulted in approximately similar ranges.

12.3.2 Occupational exposures

Occupational exposure is predominantly at power frequencies and their harmonics. Magnetic field exposure in the workplace can be up to approximately 10 mT and this is invariably associated with the presence of conductors carrying high currents. In the electrical supply industry, workers may be exposed to electric fields up to 30 kV m⁻¹, which induce electric fields in the body and lead to increased occurrence of contact currents and microshocks.

12.4 Exposure-response assessment

Exposure-response assessment is the process of characterizing the relationship between the exposure received by an individual and the occurrence of an effect. There are many ways in which exposure-response relationships can be evaluated and a number of assumptions must be used to conduct such assessments.

12.4.1 Threshold levels

For some effects there may be a continuous relation with exposure, for others a threshold may exist. There will be a certain amount of imprecision in determining these thresholds. The degree of uncertainty is reflected partly in the value of a safety factor that is incorporated in order to derive the exposure limit.

Frequency-dependent thresholds have been identified for acute effects on electrically excitable tissues, particularly those in the central nervous system. These effects result from electric fields and currents that are induced in body tissues by ELF electric or magnetic field exposure (see Chapter 5). The ICNIRP (1998a) identified a threshold current density of 100 mA m⁻² for acute changes in functions of the central nervous system (CNS: brain and spinal cord. located in the head and trunk) and recommended basic restrictions on current density induced in these tissues of 10 mA m⁻² for workers and 2 mA m⁻² for members of the public. A general consideration of neural tissue physiology suggested that these restrictions should remain constant between 4 Hz and 1 kHz, rising above and below these frequencies. More recently, the IEEE (2002) identified a threshold induced electric field strength of 53 mV m⁻¹ at 20 Hz for changes in brain function in 50% of healthy adults. Effects taken into account included phosphene induction and other effects on synaptic interactions. The IEEE recommended basic restrictions on induced electric field strength in the brain of 17.7 mV m⁻¹ in "controlled" environments and 5.9 mV m⁻¹ for members of the public. The phosphene threshold rises above 20 Hz and therefore the basic restrictions recommended by the IEEE follow a frequency-proportional law up to 760 Hz, above which restrictions are based on peripheral nerve stimulation up to 100 kHz (IEEE, 2002). The net effect is that the guidance recommended by the ICNIRP (1998a) is more restrictive than that recommended by the IEEE (2002) at power frequencies (50/60 Hz) and above (see Section 12.5.1 below). The major factor responsible for this is the difference in cut-off frequency (20 Hz for the IEEE and 1 kHz for the ICNIRP) at which thresholds for electric field strength and induced current density begin to rise (Reilly, 2005).

No thresholds have not been identified for chronic effects.

12.4.2 Epidemiological methods

The most common means of characterizing an exposure-response relationship in epidemiology is through the derivation of estimates of relative risk or the odds ratio per unit of exposure or across exposure categories.

Most epidemiological studies have used the latter method. In summary, two recent pooled analyses of the studies on ELF magnetic fields and childhood leukaemia have presented dose-response analyses. These analyses have been conducted both on the basis of exposure categories and of continuous exposure data. All these analyses show that the risk increase becomes detectable around $0.3{-}0.4~\mu T$. For exposure levels above these values, the data at present do not allow further analysis because of the small numbers of cases in the high exposure category.

12.5 Risk characterization

12.5.1 Acute effects

Exposure limits based on the acute effects on electrically excitable tissues, particularly those in the CNS, have been proposed by several international organizations. The current ICNIRP (1998a) guidelines for the general public at 50 Hz are 5 kV m⁻¹ for electrical fields and 100 μT for magnetic fields, and at 60 Hz are 4.2 kV m⁻¹ and 83 μT . For workers, the corresponding levels are 10 kV/m and 500 μT for 50 Hz and 8.3 kV m⁻¹ and 420 μT for 60 Hz. The IEEE (2002) exposure levels are 5 kV m⁻¹ and 904 μT for exposure to 60 Hz EMF for the general public. For occupational groups, the IEEE levels are 20 kV m⁻¹ and 2710 μT at 60 Hz. The differences in the guidelines, derived independently by the IEEE and the ICNIRP, result from the use of different adverse reaction thresholds, different safety factors and different transition frequencies, i.e. those frequencies at which the standard function changes slope (see section 12.4.1).

12.5.2 Chronic effects

The most common means of characterizing risks from epidemiological data for a single endpoint is to use the attributable fraction. The attributable fraction, based on an established exposure—disease relation, is the proportion of cases (of a disease) that are attributable to the exposure. The attributable fraction is based on the comparison between the number of cases in a population that occur when the population is exposed and the number that would occur in the same population if the population were not exposed, assuming that all the other population characteristics remain the same. The assumption of a causal relationship is critical to this evaluation. As noted in Chapter 11 and later in this chapter, an assumption of this kind is difficult to accept because of the numerous limitations on the epidemiological data on childhood leukaemia and ELF magnetic field exposure and a lack of supporting evidence from a large number of experimental studies. Nevertheless, a risk characterization has been performed in order to provide some insight into the possible public health impact assuming that the association is causal.

Attributable fractions for childhood leukaemia that may result from ELF magnetic field exposure have been calculated in a number of publications (Banks & Carpenter, 1988; Grandolfo, 1996; NBOSH - National Board of Occupational Safety and Health et al., 1996; NIEHS, 1999). Greenland & Kheifets (2006) have expanded on the analyses of two different sets of

pooled data on childhood leukaemia and ELF magnetic field exposure (Ahlbom et al., 2000; Greenland et al., 2000) to provide an updated evaluation covering estimates for attributable fractions in a larger number of countries than were included in the pooled analyses. In global terms, most of the information on exposure comes from industrialized countries. There are a number of regions of the world, such as Africa and Latin America, where no representative information on exposure is available. Although the odds ratios from the major study regions – North America, Europe, New Zealand and parts of Asia – are similar (and therefore estimates from a pooled analysis of data obtained in these regions could be used for the present calculation), there are substantial differences in the exposure distributions between these regions. Comparable or larger differences are expected to exist with and within other regions. Therefore, the estimates of attributable fractions calculated from the data of industrialized countries cannot be confidently generalized to cover developing countries.

Greenland & Kheifets (2006) also performed an analysis of the uncertainty in the estimates of attributable fractions, by varying the assumptions made (more details on this analysis can be found in the appendix). Using the exposure distribution from case-control studies, the calculated attributable fractions are generally below 1% for the European and Japanese studies and between 1.5 and 3% for the North American studies. Based upon the exposure surveys, the attributable fraction values vary between 1 and 5% for all areas. The confidence bounds on these numbers are relatively large. Moreover, since these calculations are highly dependent on assumptions about the exposure prevalence and distribution and on the effect of exposure on the disease, they are very imprecise. Thus, assuming that the association is causal, on a worldwide scale, the best point estimates of the calculated attributable numbers (rounded to the nearest hundred) range from 100 to 2400 childhood leukaemia cases per year that might be attributable to ELF magnetic field exposure (these numbers are derived from Figures A3 and A4 in the appendix; Kheifets, Afifi & Shimkhada, 2006), representing 0.2 to 4.9% of the total annual number of leukaemia cases, which was calculated to be around 49 000 worldwide in 2000 (IARC, 2000).

12.5.3 Uncertainties in the risk characterization

12.5.3.1 Biophysical mechanisms

The biophysical plausibility of various proposed direct and indirect interaction mechanisms for ELF electric and magnetic fields depends in particular on whether a "signal" generated in a biological process or entity by exposure to such a field can be discriminated from inherent random noise. There is considerable uncertainty as to which mechanism(s) might be relevant. Three mechanisms related to the direct interaction of fields with the human body stand out as potentially operating at lower field levels than the others: induced electric fields in networks of neural tissues, the prolongation of the lifetime of radical pairs and effects on magnetite.

12.5.3.2 Exposure metric

At present it is unknown which, if any, aspect of exposure might be harmful. Certain actions, while reducing one aspect of exposure, might inadvertently increase another aspect that, if it were a causal factor, would lead to increased risk. However, the assumptions are usually that less exposure is preferable and that reducing one aspect of exposure will also reduce any aspect that might be harmful. Neither of these assumptions is certain. In fact, some laboratory research has suggested that biological effects caused by EMF vary within windows of frequency and intensity of the fields. While such a complex and unusual pattern would go against some of the accepted tenets of toxicology and epidemiology, the possibility that it may be real cannot be ignored.

12.5.3.3 Epidemiology

The consistently observed association between average magnetic field exposure above 0.3–0.4 µT and childhood leukaemia can be due to chance, selection bias, misclassification and other factors which can potentially confound the association or a true causal relationship. Given that the pooled analyses were based on large numbers, chance as a possible explanation seems unlikely. Taking into account potential confounding factors has not changed the risk estimates and substantial confounding from factors that do not represent an aspect of the electric or magnetic fields is unlikely. Selection bias, particularly for the controls in case-control studies, may be partially responsible for the consistently observed association between ELF magnetic field exposure and childhood leukaemia. Difficulties with exposure assessment are likely to have led to substantial non-differential exposure misclassification, but this is unlikely to provide an explanation for the observed association and may in fact lead to an underestimation of the magnitude of risk. Exposure misclassification may also introduce uncertainty into the potential dose-response relation. Because the estimates of the attributable fraction are calculated from the relative risks and exposure prevalence, and since both are affected by exposure misclassification, the attributable fraction may also be affected by exposure misclassification. However, the effect on the relative risk and on the exposure misclassification tends to work in opposite directions.

12.6 Conclusions

Acute biological effects have been established for exposure to ELF electric and magnetic fields in the frequency range up to 100 kHz that may have adverse consequences on health. Therefore, exposure limits are needed. International guidelines exist that have addressed this issue. Compliance with these guidelines provides adequate protection.

Consistent epidemiological evidence suggests that chronic lowintensity ELF magnetic field exposure is associated with an increased risk of childhood leukaemia. However, the evidence for a causal relationship is lim-

DEIS Comments (MGC) - Attachment 7, Page 47 ited, therefore exposure limits based upon epidemiological evidence are not recommended, but some precautionary measures are warranted.

13 PROTECTIVE MEASURES

13.1 Introduction

With 25 years of research into possible health risks from ELF fields, much knowledge and understanding have been gained, but important scientific uncertainties still remain. Acute effects on the nervous systems have been identified and these form the basis of international guidelines. Regarding possible long-term effects, epidemiological studies suggest that everyday, low-intensity ELF magnetic field exposure poses a possible increased risk of childhood leukaemia, but the evidence is not strong enough to be considered causal and therefore ELF magnetic fields remain classified as possibly carcinogenic. The evidence is weaker for other studied effects, including other types of cancers in both children and adults, depression, suicide, reproductive dysfunction, developmental disorders, immunological modifications, neurological disease and cardiovascular disease.

Given the lack of conclusive data on possible long-term adverse health effcts decision-makers are faced with a range of possible measures to protect public health. The choices to be made depend not only on the assessment of the scientific data, but also on the local public health context and the level of concern and pressure from various stakeholders.

This chapter describes public health measures for the management of ELF risks. The scientific basis for current international EMF standards and guidelines is reviewed, followed by a summary of existing EMF policies. The use of precautionary-based approaches is discussed and recommendations are provided for protective measures considered to be appropriate given the degree of scientific uncertainty.

In the context of this chapter the collective term "policy-makers" refers to national and local governmental authorities, regulators and other stakeholders who are responsible for the development of policies, strategies, regulations, technical standards and operational procedures.

13.2 General issues in health policy

13.2.1 Dealing with environmental health risks

Most risk analysis approaches that deal with the impacts on health of a particular agent include three basic steps.

The first step is to identify the health risk and establish a risk profile or risk framing. This entails a brief description of the health context, the values expected to be placed at risk and the potential consequences. It also includes prioritizing the risk factor within the overall national public and occupational health context. This step would also comprise committing resources and commissioning a risk assessment.

The second step is to perform a risk assessment (hazard identification, exposure assessment, exposure-response assessment and risk characterization), involving a scientific evaluation of the effects of the risk factor as

carried out in this document (see Chapter 12). Some countries have the resources to undertake their own scientific evaluation of EMF health-related effects through a formal health risk assessment process (for example, the EMF RAPID programme in the United States, NIEHS, 1999) or through an independent advisory committee (for example, the Independent Advisory Group on Non-Ionizing Radiation in the United Kingdom, AGNIR, 2001b). Other countries may go through a less formal process to develop science-based guidelines or a variation on these.

Finally, risk management strategies need to be considered, taking into account that there is more than one way of managing all health risks. Specifically, appropriate management procedures need to be devised for complex, controversial and uncertain risks. The aim in these cases is to identify ways of coping with uncertainty and inadequate information by developing sound decision-making procedures, applying appropriate levels of precaution and seeking consensus in society. The term "risk management" encompasses all of those activities required to reach decisions on whether a risk requires elimination or reduction. Risk management strategies can be broadly classified as regulatory, economic, advisory or technological, but these categories are not mutually exclusive. Thus a broad collection of elements can be factored into the final policy-making or rule-making process. such as legislative mandates (statutory guidance), political considerations, socio-economic values, costs, technical feasibility, the population at risk, the duration and magnitude of the risk, risk comparisons and the possible impact on trade between countries. Key decision-making factors such as the size of the population, resources, the costs of meeting targets, the scientific quality of the risk assessment and subsequent managerial decisions vary enormously from one decision context to another. It is also recognized that risk management is a complex multidisciplinary procedure which is seldom codified or uniform, is frequently unstructured and can respond to evolving input from a wide variety of sources. Increasingly, risk perception and risk communication are recognized as important elements that must be considered for the broadest possible public acceptance of risk management decisions.

The process of identifying, assessing and managing risks can helpfully be described in terms of distinct steps, as described in a report of the US Presidential/Congressional Commission on Risk Assessment and Risk Management (1997) which emphasizes the analysis of possible options, clarification of all stakeholders' interests and openness in the way decisions are reached. In reality, however, these steps overlap and merge into one other, and should ideally be defined as an iterative process that includes two-way feedback and stakeholder involvement at all stages (Figure 10).

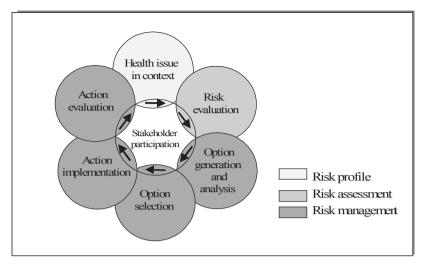


Figure 10. Dealing with risk: A risk analysis process that includes identifying, assessing and managing risks.

13.2.2 Factors affecting health policy

For policy-makers, scientific evidence carries substantial weight, but is not the exclusive criterion. Final decisions will also incorporate social values, such as the acceptability of risks, costs and benefits and cultural preferences. The question policy-makers strive to answer is "What is the best course of action to protect and promote health?"

Governmental health policies are based on a balance of "equity", i.e. the right of each citizen to an equitable level of protection and "efficiency", where cost-benefit or cost-effectiveness is important. The level of risk deemed acceptable by society depends on a number of factors. Where there is an identified risk, the value that society places on the reduction of risk or disease arising from a particular agent, technology or intervention is based on the assumption that the reduction will actually occur. For involuntary exposures a notional (*de minimis*) value of lifetime mortality risk of 1 in 100 000 is accepted as a general threshold (with 1 in a million as an ideal goal) below which the risk is considered to be acceptable or impractical to improve on (WHO, 2002). For example, the risk of ionizing radiation exposure from radon is reasonably well-characterized and the exposure should be reduced so that it does not cause radiation-induced cancer in more than one per 100 000 individuals over their lifetime.

In developing policy, regulators try to maximize the benefits and minimize societal costs. The following issues are considered to be part of this process.

• Public health/safety – A major objective of policy is to reduce or eliminate harm to the population. Harmful effects on health are

usually measured in terms of morbidity caused by the exposure and the probability that an effect would occur. They could also be measured in terms of extra cases of disease or death due to exposure, or of the number of cases avoided by reducing exposure.

- Net cost of the policy The cost, referring to more than simply the monetary expense, of the policy for society as a whole, without considering any distribution of the cost, consists of several components: (a) the direct cost imposed on the entire society for any measures taken; (b) the indirect cost to society, for example, resulting from less than optimal use of the technology; and (c) cost reduction created by the policy, for example, faster implementation of a beneficial technology.
- Public trust The degree of public trust in the policy and the degree of its acceptance as an effective means to adequately protect public health is an important objective in many countries. Moreover, the public's feeling of safety is important in itself, since the WHO definition of health addresses social well-being and not only the absence of disease or infirmity (WHO, 1946).
- Stakeholder involvement A fair, open and transparent process is essential to good policy-making. Stakeholder involvement includes participation at each stage of policy development and opportunities to review and comment on a proposed policy prior to its implementation. Such a process may legitimately result in outcomes different from those that would be chosen by scientific experts or decision-makers alone.
- Non-discriminatory treatment of sources All sources should receive the same attention when considering exposure (for example, for ELF fields, when reducing magnetic fields that result from grounding practices in the home, household appliances, power lines and transformers). The policy should focus on the most cost-effective option for reducing exposure. The policy-maker must determine whether (a) different consideration should be given to new or existing facilities and (b) there is justification for a different policy for non-voluntary and voluntary exposure. For further information, see the statement of the European Commission on the precautionary principle (EC, 2000).
- Ethical, moral, cultural and religious constraints —
 Notwithstanding stakeholder consultation, individuals and groups
 may differ in their views regarding whether a policy is ethical,
 moral and culturally acceptable or in agreement with religious
 beliefs. These issues can affect the implementation of a policy and
 need to be considered.
- Reversibility The consequences of implementing a policy must be carefully considered. Policies need to be balanced and based on

current information and include sufficient flexibility to be modified as new information becomes available.

13.3 Scientific input

Science-based evaluations of any hazards caused by EMF exposure form the basis of international guidelines on exposure limits and provide an essential input to public policy response. Criteria and procedures for determining limit values are outlined in the WHO Framework for Developing Health-based EMF Standards (WHO, 2006a).

13.3.1 Emission and exposure standards

Standards contain technical specifications or other precise criteria that are used consistently as rules, guidelines or definitions of characteristics to ensure that materials, products, processes and services are fit for their purpose. In the context of EMF they can be emission standards, which specify limits of emissions from a device, measurement standards, which describe how compliance with exposure or emission standards may be ensured, or exposure standards, which specify the limits of human exposure from all devices that emit EMF into a living or working environment.

Emission standards set various specifications for EMF-emitting devices and are generally based on engineering considerations, for example to minimize electromagnetic interference with other equipment and/or to optimize the efficiency of the device. Emission standards are usually developed by the International Electrotechnical Commission (IEC), the Institute of Electrical and Electronic Engineers (IEEE), the International Telecommunications Union (ITU), the Comité Européen de Normalisation Electrotechnique / European Committee for Electrotechnical Standardization (CENELEC), as well as other independent organizations and national standardization authorities.

While emission standards are aimed at ensuring, inter alia, compliance with exposure limits, they are not explicitly based on health considerations. In general, emission standards are intended to ensure that exposure to the emission from a device will be sufficiently low that its use, even in proximity to other EMF-emitting devices, will not cause exposure limits to be exceeded.

Exposure standards that limit human EMF exposure are based on studies that provide information on the health effects of EMF, as well as the physical characteristics and the sources in use, the resulting levels of exposure and the people at risk. Exposure standards generally refer to maximum levels to which whole or partial body exposure is permitted from any number of sources. This type of standard normally incorporates safety factors and provides the basic guide for limiting personal exposure. Guidelines for such standards have been issued by the International Commission on Non-Ionizing Radiation Protection (ICNIRP, 1998a), the Institute of Electrical and Electronic Engineers (IEEE, 2002) and many national authorities. These have been discussed in Chapter 12. While some countries have adopted the

ICNIRP guidelines, others use them as the de facto standard without giving them a legal basis (WHO, 2006b).

13.3.2 Risk in perspective

There is scientific uncertainty as to whether chronic exposure to ELF magnetic fields causes an increased risk of childhood leukaemia. In addition, given the small estimated effect resulting from such a risk, the rarity of childhood leukaemia, the rarity of average exposures higher than 0.4 μT and the uncertainty in determining the relevant exposure metric (see section 12.5.3), it is unlikely that the implementation of an exposure limit based on the childhood leukaemia data and aimed at reducing average exposure to ELF magnetic fields to below 0.4 μT , would be of overall benefit to society.

The actual exposures of the general public to ELF magnetic fields are usually considerably lower than the international exposure guidelines. However, the public's concern often focuses on the possibility of long-term effects caused by low-level environmental exposure. The classification of ELF magnetic fields as a possible carcinogen has triggered a reappraisal by some countries of whether the exposure limits for ELF provide sufficient protection. These reappraisals have led a number of countries and local governments to develop precautionary measures as discussed below.

13.4 Precautionary-based policy approaches

Since protecting populations is part of the political process, it is expected that different countries may choose to provide different levels of protection against environmental hazards, responding to the factors affecting health policy (see section 13.2.2). Various approaches to protection have been suggested to deal with scientific uncertainty. In recent years, increased reference has been made to precautionary policies, and in particular the Precautionary Principle.

The Precautionary Principle is a risk management tool applied in situations of scientific uncertainty where there may be need to act before there is strong proof of harm. It is intended to justify drafting provisional responses to potentially serious health threats until adequate data are available to develop more scientifically based responses. The Precautionary Principle is mentioned in international law (EU, 1992; United Nations, 1992) and is the basis for European environmental legislation (EC, 2000). It has also been referred to in some national legislation, for example in Canada (Government of Canada, 2003), and Israel (Government of Israel, 2006). The Precautionary Principle and its relationship to science and the development of standards have been discussed in several publications (Foster, Vecchia & Repacholi, 2000; Kheifets, Hester & Banerjee, 2001).

13.4.1 Existing precautionary ELF policies

With regard to possible effects from chronic ELF exposure, policy-makers have responded by using a wide variety of precautionary policies based on cultural, social, and legal considerations. These include the impor-

tance given to avoiding a disease that affects mostly children, the acceptability of involuntary, as opposed to voluntary, exposures and the different importance given to uncertainties in the decision-making process. Some measures are mandatory and required by law, whereas others are voluntary guidelines. Several examples are presented below.

- Prudent avoidance This precautionary-based policy was developed for power-frequency EMF. It is defined as taking steps to lower human exposure to ELF fields by redirecting facilities and redesigning electrical systems and appliances at low to modest costs (Nair, Morgan & Florig, 1989). Prudent avoidance has been adopted as part of policy in several countries, including Australia, New Zealand and Sweden (see Table 85). Low-cost measures that can be taken include routing new power lines away from schools and phasing and configuring power line conductors to reduce magnetic fields near rights-of-way.
- Passive regulatory action This recommendation, introduced in the USA for the ELF issue (NIEHS, 1999), advocates educating the public on ways to reduce personal exposure, rather than setting up actual measures to reduce exposure.
- Precautionary emission control This policy, implemented in Switzerland, is used to reduce ELF exposure by keeping emission levels as low as "technically and operationally feasible". Measures to minimize emissions should also be "financially viable" (Swiss Federal Council, 1999). The emission levels from a device or class of devices are controlled, while the international exposure limits (ICNIRP, 1998a) are adopted as the maximum level of human exposure from all sources of EMF.
- Precautionary exposure limits As a precautionary measure, some countries have reduced limits on exposure. For example, in 2003, Italy adopted ICNIRP standards but introduced two further limits for EMF exposure (Government of Italy, 2003): (a) "attention values" of one tenth of the ICNIRP reference levels for specific locations, such as children's playgrounds, residential dwellings and school premises, and (b) further restrictive "quality goals" which only apply to new sources and new homes. The chosen values for 50 Hz, 10 μT and 3 μT respectively, are arbitrary. There is no evidence of possible acute effects at that level nor evidence from epidemiological studies of leukaemia which suggests that an exposure of 3 μT is safer than an exposure of 10 or 100 μT.

Other examples of various types of precautionary policies applied to power-frequency field exposure are given in Table 86 (Kheifets et al., 2005). A complete database of EMF standards worldwide is provided on the website of the WHO International EMF Project (WHO, 2006b).

Table 85. Examples of pr	precautionary approaches	ches	
Precautionary approach		Country	Measures
Prudent avoidance		New Zealand Australia Sweden	Adopt ICNIRP guidelines and add low-cost voluntary measures to reduce exposure
Passive regulatory action		USA	Educate the public on measures to reduce exposure
Precautionary emission control	introl	Switzerland	Adopt ICNIRP guidelines and set emission limits
Precautionary exposure limits	nits	Italy	Decrease exposure limits using arbitrary reduction factors
Table 86. Various approa	iches to EMF exposu	Table 86. Various approaches to EMF exposure limitation for the general public ^a	lic a
Agency / country	Limits		Comments
Precautionary policies bas	based on exposure limits		
Israel, 2001	1 µT		Newly constructed facilities
Italy, 2003	100 µT		
	10 µT		Attention value applies to exposures that occur for more than 4 hours per day
	3 µТ		Quality target that only applies to new lines and new homes
USA	15–25 µТ		Under maximum load conditions. Established by regulations in some states (e.g. Florida) and by informal guidelines in others (e.g. Minnesota)
	0.2-0.4 µT		Adopted in some local ordinances (e.g. Irvine, California)

Table 86. Continued		
Precautionary policies base	Precautionary policies based on separation of people from sources of exposure	
Ireland, 1998	No new transmission lines or substations closer than 22 metres to an existing school or building	Local government will not grant construction permits for electrical power installations in the vicinity of schools and daycare centres
The Netherlands, 2005	Increased distance between power lines and places were children can spend significant amounts of time to ensure that their mean exposure will not exceed 0.4 µT	For new buildings near existing power lines, or new power lines near existing buildings
USA	Restrictions on sitting new schools close to existing elec- Adopted by the California Department of Education tric transmission lines	
	New lines must be buried unless technically infeasible and Adopted by the State of Connecticut there must be buffer zones near residential areas, schools, day care facilities and youth camps	Adopted by the State of Connecticut Model of Connecticut Model of Connecticut
Precautionary policies based on costs	d on costs	
USA	No- or low-cost alterations to the design or routing if substantial field reduction (more than 15%) can be achieved; 4% used as benchmark of project cost	Adopted by the Public Utilities Commission for the State of DO California
Precautionary policies base	Precautionary policies based on non-quantitative objectives	
Australia, 2003	Reduction of exposure where it is easily achievable	
Sweden, 1996	Reduction of exposure with no recommendations regard- Includes taking into account EMF when designing new ing levels away from sensitive areas	Includes taking into account EMF when designing new transmission and distribution facilities and siting them way from sensitive areas
^a Source: Kheifets et al., 20	2005.	

Source: Kneirets et al., 20

13.4.2 Cost and feasibility

The problem faced by the regulator is how to determine and evaluate the trade-off between various objectives and constraints. If zero tolerance to risk is desired, then it implies that cost is of no importance, which is problematic in a world with limited resources. On the other hand, accepting the use and introduction of technologies, provided that they have not been proven hazardous, disregards any potential health effects and may have a cost that society is not willing to pay.

From a utilitarian perspective, policy decisions cannot be made without a consideration of costs and these costs must be placed in context with the benefits. The costs and benefits of policy options should be considered at the broadest level and also presented in such a way that the costs and possible benefits to various stakeholders can be understood. All costs should be included, whether borne by industry, consumers or others. Even when allowing for the legitimate desire of society to err on the side of safety, it is likely that it will be difficult to justify more than very low-cost measures to reduce exposure to ELF fields.

Examples of approaches to considering the costs and benefits of precautionary actions on EMFs can be found in various countries. One example of an assessment of the costs of possible actions to reduce fields from power lines is in the Netherlands (Kelfkens et al., 2002). Here national geographical records were used to identify homes close to power lines, and hence to calculate the numbers of homes exposed to various levels of ELF magnetic fields. Four possible interventions were then considered: vectorsequence rearrangement, phase conductor splitting, line relocation and undergrounding, and each of these were costed for those lines where people live nearby. The effect of each of these measures on the change in distance of various field levels to the line was also calculated. Dividing the cost by the number of homes removed from exposure to the given field level provided an "average cost per dwelling gained". For 0.4 µT, this cost per dwelling for vector-sequence rearrangement, phase conductor splitting, line relocation and undergrounding was €18,000, €55,000, €128,000 and €655,000, respectively. An analysis of this kind is useful to policy-makers as it allows for the consideration and comparison of technical measures with other measures, for example, the relocation of power lines or dwellings.

Extensive "what if" policy analyses relating to EMFs from power lines and in schools were carried out in California in the late 1990s. The authors considered both a utilitarian and duty ethic approach to the question: "How certain do we need to be of the extent of the disease impact from EMFs before we would take low-cost or expensive EMF avoidance measures?" The results are summarized in a "Policy Options" document. Computer models were developed which allow users to investigate the impact of several variables, such as costs, probability of disease and extent of disease (von Winterfeldt et al., 2004). The cost–benefit analysis tended to suggest that avoidance measures at modest cost could be justified from a cost–benefit viewpoint below a "beyond a reasonable doubt" level of scientific certainty.

This approach has not been formally implemented in California, where the no- or low-cost policy has been recently reaffirmed.

Five Swedish governmental authorities published "Guidance for Decision-makers" in 1996, in which caution was recommended at reasonable expense. Examples of costing estimates were provided for several case studies. Based on their definition of the precautionary principle, measures should be considered when the fields deviate strongly from what can be deemed normal in the environment concerned (NBOSH, 1996).

When attempting to place a notional value on the benefit of preventing fatalities or cases of disease, extensive literature is available from areas other than EMFs. The two main approaches to obtaining a financial value are "human capital" and "willingness to pay". "Human capital" attempts to calculate the loss to society of a fatality, for example, by estimating the lost wages that would have been earned by that person during the rest of their life and in more sophisticated analyses including, for example, the cost to society of treating disease etc. "Willingness to pay" attempts to observe what individuals or society as a whole are willing to pay to prevent ill health or fatality, e.g. by looking at the extra salary paid to people in high-risk occupations or the amount that people are willing to pay to avoid living in an earthquake zone.

Both the "human capital" and "willingness to pay"-approaches are society-specific. For example, a WHO analysis of "The cost of diabetes in Latin America and Caribbean" (Alberto et al., 2003) used the human capital approach, calculating lost earings resulting from premature death and disability, and valued premature death in Latin America and the Caribbean at \$37,000 per person. But a WHO analysis (Adams et al., 1999) of the economic value of premature death attributed to environmental tobacco smoke cites an EPA study from the USA which placed the "willingness" to pay" value of human life lost at \$4.8 million per person and another study that places the value of human life lost at \$5 million per person. The wage-risk trade-off method was used to determine this amount.

These examples provide an insight into how some researchers and national or local authorities have analysed several scenarios, assuming the potential health risk from ELF exposure to be important enough to implement precautionary measures. For countries without the resources to conduct such an exercise, recommendations are provided below that the Task Group considers appropriate, based on all the evidence considered.

13.5 Discussion and recommendations

Countries are encouraged to adopt international science-based guidelines. In the case of EMF, the international harmonization of standard-setting is a goal that countries should aim for (WHO, 2006a).

If precautionary measures are considered to complement the standards, they should be applied in such a way that they do not undermine the science-based guidelines.

Table 87. Factors relevant to the analysis of each policy option ^a	s of each policy option ^a	
Option	Relevant factors in considering benefits	Relevant factors in considering costs
Do nothing	Childhood leukaemia is a relatively rare disease, and only a small proportion of the population is exposed to levels mentioned in epidemiological studies (i.e. estimated time-weighted average above 0.3 or 0.4 µT).	No possibility of reducing burden of disease. No progress towards removal of uncertainties and better knowledge in future. Undermines trust in authorities.
	There are many uncertainties regarding the effectiveness of policies, which could be reduced with scientific progres.	Concerned clitzers may take matters into trieir own hands.
	When the only available options are costly it may be more appropriate not to take formal action. Allows for the adaptation of policy as evidence emerges.	
Research	Reduces uncertainty and facilitates better decision- Diversion of resources from higher priority areas. making. May delay actions awaiting research results. Contributes to the scientific base.	
	Helps in developing solutions.	aiment 7, Fage 39

Table 87. Continued			
Option		Relevant factors in considering benefits	Relevant factors in considering costs
Communication		A knowledgeable public - can better evaluate the acceptability of different levels of ELF risks - can reduce public concern due to misperceived ELF risks - can increase trust in those providing the information.	Possibility of giving rise to unjustified alarm or concern. May have limited effectiveness where the understanding of exposure is difficult or where exposure is involuntary and hard to avoid.
		A knowledgeable public and workers - can be involved in the decision-making process regarding ELF sources - can make informed decisions on what appliances to purchase or how to place them so as to minimize exposure - can influence market forces to design sources in order to minimize exposure (e.g. electric blankets).	DEIS Comments (MG
Mitigation	Changes to plan- ning of new facili- ties	Requires alternative technical designs be presented for the construction of new facilities. Avoid unnecessary exposure by comparing different planning scenarios so as to minimize exposure. Costs may include sterilization of land, devaluation of property, and compensation payments. Use of best available technology. Possibility of setting a precedent for future projects stage of new installations.	

Table 87. Continued			
Option		Relevant factors in considering benefits	Relevant factors in considering costs
Mitigation	Engineering changes of existing facilities	Reduction of exposure by taking protective measures such as installing shielding, changing wiring practices in burses and in distribution or transmiss.	A significant part of the cost may be in identifying the instances rather than remediation.
		sion systems (split phasing, raising ground clear- ances, undergrounding etc.).	Changes introduced to existing installations involve a higher cost.
			Costs may include sterilization of land, devaluation of property and compensation payments.
	Engineering changes to appli- ances	Reduction of exposure to magnetic fields.	Increased cost (or increased size or weight) of SS appliances.
National standards	Exposure limits	May increase public confidence in the authority's action to protect health.	May undermine science-based guidelines.
			May give false sense of security.
			May hinder incentives for further reduction of undue exposure.
			Cost of compliance.
			Difficult to move towards less stringent standards if a justified by new scientific evidence.
a With the exception of t	the first option, all th	he first option, all the options are evaluated in relation to "doing nothing" rather than adopting international guidelines.	rather than adopting international guidelines.

As a result of considering the various options, policy makers will select and implement appropriate, country-specific measures for the protection of the general public and workers from exposure to ELF fields. Factors relevant to the evaluation of each policy option are given in Table 87. Precautionary measures are generally implemented through voluntary codes, encouragement and collaborative programmes rather than through mandatory enforcement, and should be seen as interim policy tools.

Risk perception and communication

The lack of policy harmonization worldwide is one of many factors that may exacerbate public anxiety. People's perceptions of a risk depend on personal factors, external factors and the nature of the risk (Slovic, 1987). Personal factors include age, sex, and cultural or educational backgrounds, while external factors comprise the media and other forms of information dissemination, the current political and economic situation, opinion movements and the structure of the regulatory process and political decision-making in the community.

The nature of the risk can also lead to different perceptions depending on the degree of control the public has over a situation, fairness and equity aspects in locating EMF sources and fear of specific diseases (for example, cancer versus headache). The greater the number of factors that contribute to the public's perception of risk, the greater the potential for public concern. Public concern can be reduced through information and communication between the public, scientists, governments and industry. Effective risk communication is not only a presentation of the scientific calculation of risk, but also a forum for discussion on broader issues of ethical and moral concern (WHO, 2002).

Consultation

The acceptability of the risks of ELF fields, relative to other environmental health risks, is ultimately at least as much about political and societal values and judgements as it is about scientific information. To establish public trust and confidence, stakeholders need to be involved in decision-making at the appropriate time. ELF stakeholders include government agencies, scientific and medical communities, advocacy groups, consumer protection organizations, environmental protection organizations, other affected professionals such as planners and property professionals, and industry including the electricity industry and appliance manufacturers. While there will not always be consensus on such issues, the position taken should be transparent, evidence-based and able to withstand critical scrutiny.

Need for periodic evaluation

As new scientific information becomes available, exposure guidelines and standards should be updated. Certain studies may be more likely than others to prompt a re-evaluation of the scientific basis of the guidelines and standards because of the strength of the evidence or because of the sever-

ity of the health outcome under study. Changes to standards or policy should only be made after a proper assessment of the science base as a whole, to ensure that the conclusions of the research in a given area are consistent.

Exposure reduction

In recommending precautionary approaches, an overriding principle is that any actions taken should not compromise the essential health, social and economic benefits of electric power. In the light of the current scientific evidence and given the important remaining uncertainties, it is recommended that an assessment be conducted of the impact of any precautionary approach on the health, social and economic benefits of electric power. Provided that these benefits are not compromised, implementing precautionary procedures to reduce exposures is reasonable and warranted. The costs of implementing exposure reductions will vary from one country to another, making it very difficult to provide a general recommendation for balancing the costs against the risk from ELF fields. Given the weakness of the evidence for a link between exposure to ELF magnetic fields and childhood leukaemia and the limited potential impact on public health, the benefits of exposure reduction on health are unclear and thus the cost of reducing exposure should be very low.

13.5.1 Recommendations

In view of the above, the following recommendations are given.

- Policy-makers should establish guidelines for ELF field exposure for both the general public and workers. The best source of guidance for both exposure levels and the principles of scientific review are the international guidelines.
- Policy-makers should establish an ELF EMF protection programme that includes measurements of fields from all sources to ensure that the exposure limits are not exceeded either for the general public or workers.
- Provided that the health, social and economic benefits of electric power are not compromised, implementing very low-cost precautionary procedures to reduce exposures is reasonable and warranted.
- Policy-makers and community planners should implement very low-cost measures when constructing new facilities and designing new equipment including appliances.
- Changes to engineering practice to reduce ELF exposure from equipment or devices should be considered, provided that they yield other additional benefits, such as greater safety, or involve little or no cost.

- When changes to existing ELF sources are contemplated, ELF field reduction should be considered alongside safety, reliability and economic aspects.
- Local authorities should enforce wiring regulations to reduce unintentional ground currents when building new or rewiring existing facilities, while maintaining safety. Proactive measures to identify violations or existing problems in wiring would be expensive and unlikely to be justified.
- National authorities should implement an effective and open communication strategy to enable informed decision-making by all stakeholders; this should include information on how individuals can reduce their own exposure.
- Local authorities should improve planning of ELF EMF-emitting facilities, including better consultation between industry, local government, and citizens when siting major ELF EMF-emitting sources.
- Government and industry should promote research programmes to reduce the uncertainty of the scientific evidence on the health effects of ELF field exposure.

APPENDIX: QUANTITATIVE RISK ASSESSMENT FOR CHILDHOOD LEUKAEMIA

Although a causal relationship between magnetic fields and child-hood leukaemia has not been established, estimates of the possible public health impact which assume causality are presented below in order to provide a potentially useful input into policy analysis under different scenarios (Kheifets, Afifi & Shimkhada, 2006).

The public health impact of exposure to an agent can be based on calculations of attributable fractions. The attributable fraction, based on an established exposure-disease relation, is the proportion of the case load (of disease) that is attributable to the exposure assuming there is a causal relationship. The attributable fraction is based on the difference between the number of cases in a population that occur when the population is subject to a given exposure distribution, and the number that would occur in the same population if that distribution were changed (e.g. if exposure was reduced or eliminated by an intervention). In this calculation, it is assumed that all other population characteristics remain the same. Hence, the attributable fraction can be used to estimate the degree of incidence reduction that would be expected if exposure were reduced. Since the epidemiological literature has consistently found elevated risk of childhood leukaemia at ELF magnetic field exposure levels above 0.3 μ T for the arithmetic mean and above 0.4 μ T for the geometric mean, attributable-fraction estimates for these (relatively) high-level exposures allow the estimated impact on disease incidence of eliminating or reducing exposure above these levels, assuming the relation between exposure and leukaemia incidence is causal.

There are two basic pieces of information needed to make a crude estimate of the attributable fraction: (1) an estimate of the exposure effect on the disease and (2) the prevalence of exposure in the population.

A.1 Exposure distribution

In evaluating the risks from exposure to any biologically active agent, physical, biological, or chemical, it is important to understand the distribution and magnitudes of the exposures in the general population. In order to effectively quantify the risks of childhood leukaemia, if any, from exposure to ELF magnetic fields, we must first get some estimate of the degree of exposure in children. As noted in Chapter 2, these exposures will different from country to country due to a number of factors, most notably the frequency and voltage used for power distribution.

There are two types of studies from which the exposure distribution is extracted: (1) exposure surveys to provide estimates of the exposure prevalence in children (P_0), and (2) case series from case-control studies to provide estimates of P_0 and P_1 where P_1 is the exposure prevalence in children with childhood leukaemia. Use of each of these sources provides some advantage. Case-control studies provide most relevant measurements of exposure, but may be biased, if for example, restrictions on the population (e.g. to live within a certain distance of power lines) make the case exposure

prevalence in the study different from the population prevalence P_1 ; this renders unusable the case and control prevalences from studies with exposure-related restrictions. Even if the cases are representative, the controls will not be if matching has been done and the matching factors are associated with exposure; in that case the P_0 estimate from the study will be biased upward, toward P_1 ; fortunately, the most common matching factors were child's age and sex, which appear to be almost independent of exposure in the studies (Greenland, 2001; 2005). Exposure surveys, on the other hand, included both children and adults, as well as personal measurements throughout the day, that are thus only tangentially related to the exposure in the child's bedroom. At the very least the use of both of these sources provides a range of relevant exposures and subsequently a range of attributable fractions and numbers for consideration

In contrast, in the case-control studies, the exposure distributions of the cases were used. For those case-control studies included in each pooled analysis, the exposure distribution reported in the pooled analysis was used. For studies not included in either pooled analysis, the exposure distribution was extracted directly from the study. (See Tables A.1 and A.2 for details of all the exposure distributions used.) It is assumed that there are no significant difference in the exposure distributions based on exposure surveys and on case-control studies. Furthermore, it is assumed that exposures obtained using personal measures are equivalent to those from household measurements, regardless of length of time of measurement.

Globally, there is disproportionately more information on exposure from industrialized countries; and among these countries, the majority of the studies have been in the USA and, to a lesser extent, in Europe. There are a number of regions of the world, such as Africa and Latin America, where no representative information on exposure is available. Furthermore, there can be substantial differences in the exposure distributions within a region; for example, exposures in Korea are probably very different from those in China and India. This poses a difficulty for a global estimation of attributable fractions and numbers since these are highly dependent on the exposure distribution, hence emphasizing the need for more data on exposure levels worldwide.

A.2 Exposure-response analysis using attributable fraction estimates for EMF and childhood leukaemia

If no adjustment for covariates is needed, the values of the estimates of (1) the exposure effect on the disease and (2) the prevalence of exposure in the population are simply entered into the unadjusted (crude) attributable fraction formula (Levin, 1953):

$$AF_p = P_0(RR - 1)/[P_0(RR - 1) + 1]$$

where AF_p is the estimated attributable fraction and RR is the risk ratio estimate. If confounding is present, both RR and P₀ should be adjusted (Rothman & Greenland, 1998), but in practice only an adjusted estimate for